of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device PCD™ Tachyarrhythmia Control Device Model 72171B. PCD™ Tachyarrhythmia Control Device Model 72171B is an implantable, multiprogrammable, automatic tachyarrhythmia control device designed to automatically detect episodes of ventricular tachycardia (VT) or ventricular fibrillation (VF) and deliver therapies. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for PCD™ Tachyarrhythmia Control Device Model 72171B (U.S. Patent No. 4,052,991) from Medtronic, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated May 24, 1993, advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of PCD™ Tachyarrhythmia Control Device Model 72171B represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that the FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for PCD™ Tachyarrhythmia Control Device Model 72171B is 912 days. Of this time, 208 days occurred during the testing phase of the regulatory review period, while 704 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun:* August 16, 1990. FDA has verified the applicant's claim that the IDE required under section 520(g) of the Federal Food, Drug, and Cosmetic Act became effective on August 16, 1990.

2. *The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act*: March 11, 1991. The applicant claims March 8, 1991, as the date the premarket approval application (PMA) for PCD™ Tachyarrhythmia Control Device Model 72171B (PMA P900061) was initially submitted. However, FDA records indicate that PMA P900061 was initially submitted on March 11, 1991.

3. *The date the application was approved*: February 11, 1993. FDA has verified the applicant's claim that PMA P900061 was approved on February 11, 1993.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks two years of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 12, 1993, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before February 7, 1994, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 3, 1993.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 93–19046 Filed 8–9–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 93E–0090]

Determination of Regulatory Review Period for Purposes of Patent Extension; TILADE®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for TILADE® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John S. Ensign, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product TILADE® (nedocromil sodium). TILADE® is indicated for maintenance therapy in the management of patients with mild to moderate bronchial asthma. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for TILADE® (U.S. Patent No. 4,474,787) from Fisons plc, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated March 11, 1993, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the

approval of TILADE® represented the first commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for TILADE® is 3,495 days. Of this time, 1,365 days occurred during the testing phase of the regulatory review period, while 2,130 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* June 8, 1983. The applicant claims March 6, 1983, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND was placed on clinical hold on March 4, 1983, and was removed from hold on June 8, 1983. Therefore, the IND effective date is June 8, 1983.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* March 3, 1987. The applicant claims February 27, 1987, as the date the new drug application (NDA) for TILADE® (NDA 19-660) was initially submitted. However, FDA records indicate that NDA 19-660 was initially submitted on March 3, 1987.

3. *The date the application was approved:* December 30, 1992. FDA has verified the applicant's claim that NDA 19-660 was approved on December 30, 1992.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 12, 1993, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before February 7, 1994, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 3, 1993.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 93-19048 Filed 8-9-93; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 93N-0284]

Lyphomed, Division of Fujisawa USA, Inc.; Withdrawal of Approval of a New Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new drug application (NDA) held by Lyphomed, Division of Fujisawa USA, Inc., 2045 North Cornell Ave., Melrose Park, IL 60160-1002 (Lyphomed). FDA is withdrawing approval of this application because of questions raised about the reliability of the data and information submitted to FDA in support of the application. Marketing of the drug has been discontinued, and Lyphomed has waived its opportunity for a hearing.

EFFECTIVE DATE: August 10, 1993.

FOR FURTHER INFORMATION CONTACT: Tamar Nordenberg, Center for Drug Evaluation and Research (HFD-366), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-2041.

SUPPLEMENTARY INFORMATION: Recently, FDA became aware of discrepancies concerning the data used to support approval of the following NDA held by Lyphomed:

NDA 19-229, Zinc Sulfate Injection, 1 milligram per milliliter (mg/mL), 10 and 30 mL vials.

Lyphomed has identified discrepancies in data submitted to obtain approval of the application listed above, which have raised questions about the reliability of the data. Subsequently, in a letter dated June 1, 1992, Lyphomed requested withdrawal of this NDA.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the NDA listed above, and all amendments and supplements thereto, is hereby withdrawn, effective August 10, 1993. Distribution of drug products in interstate commerce without an approved application is unlawful.

Dated: July 28, 1993.

Carl C. Peck,

Director, Center for Drug Evaluation and Research.

[FR Doc. 93-19113 Filed 8-9-93; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 93M-0251]

Tosoh Medics, Inc.; Premarket Approval of AIA-PACK PA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Tosoh Medics, Inc., Foster City, CA, for premarket approval, under section 515 of the Federal Food, Drug, and Cosmetic Act (the act), of the AIA-PACK PA. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of July 7, 1993, of the approval of the application.

DATES: Petitions for administrative review by September 9, 1993.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Peter E. Maxim, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301-427-1034.

SUPPLEMENTARY INFORMATION: On April 24, 1992, Tosoh Medics, Inc., Foster City, CA 94404, submitted to CDRH a premarket approval application (PMA) for the AIA-PACK PA. The AIA-Pack PA is designed for *in vitro* diagnostic use only for the quantitative measurement of prostate specific antigen in serum to be used to aid in the management of patients with prostatic cancer. In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Immunology Devices Panel, an FDA advisory panel, for review and